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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,582	10/31/2003	Meir Stern	85189-5300	1887

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EXAMINER	
TSAY, MARSHA M	
ART UNIT	PAPER NUMBER
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/26/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,582	STERN ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-38,40-48,50 and 53-79* is/are pending in the application.

4a) Of the above claim(s) *40-48,50 and 53-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-38 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/24/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This Office action is in response to Applicants' remarks received October 17, 2006. Claims 1-21, 39, 49, 51, 52 are canceled. Claims 40-48, 50, 53-79 are withdrawn. Claims 22-38, 56 are currently under examination.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

Priority: The priority date is October 31, 2002.

Objections and Rejections

The disclosure is objected to because of the following informalities: on page 1 of the specification, the priority data needs to be updated with a cross reference to related applications.

Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 22 has been amended to recite "exposed surface" of the liner. There is no support for the language "exposed surface" in the instant specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-25, 37 are rejected again under 35 U.S.C. 102(b) as being anticipated by Haralambopoulos (US 5958447). Haralambopoulos teaches a transdermal patch comprising a bioactive substance can be formulated as a powder, liquid, or semi-liquid, e.g. gel or emulsion, and applied between the adhesive surface of a tape and its release liner (or its backing layer, for a transfer tape) (col. 3, lines 5-20). In Figure 1, Haralambopoulos teaches an active substance (or mixture of substances) in powder form is sprinkled, deposited, or spread uniformly as a thin layer on an exposed adhesive surface of a patch of a prefabricated pressure sensitive adhesive tape, which is comprised of a backing layer and a pressure sensitive adhesive matrix (col. 6 lines 45-50; claims 22-25). Haralambopoulos teaches the incorporation of powdered ascorbic acid into a transdermal patch (col. 8 lines 6-9; lines 22-25). Although Haralambopoulos does not specifically teach the elements of below 20% by weight of water and wherein the active agent remains stable for at least 3 months, claim 37 is still anticipated by Haralambopoulos because

Haralambopoulos teaches the active substance is in powder and/or dry form and therefore, will contain below 20% by weight of water and be stable for at least three months at about 22°C by inherency.

Applicants have currently amended instant claim 1 to include the elements, a liner and present on an exposed surface of the liner. In their remarks, Applicants assert Haralambopoulos teaches powdered patches wherein an active substance in a powder form becomes incorporated or embedded in the adhesive matrix of a transdermal patch by application of heat and/or pressure. Thus, the active substance in a powder form is embedded into the adhesive matrix of the transdermal patch. In contrast, the present invention discloses that the pharmaceutical composition comprising the active agent is localized on the surface of the liner of the printed patch on which the pharmaceutical composition is applied. Applicants point to paragraphs [0109] and [0195] and Figure 8 for support. Applicants further assert that no pressure is involved in making the printed patches of the present invention as such patches are made by simply drying and point to paragraphs [0109] and [0152] for support. Applicant's arguments have been fully considered but they are not persuasive.

In Figure 1 of the Haralambopoulos reference, Haralambopoulos teaches a patch of a prefabricated, pressure sensitive adhesive tape having a thin layer of a powdered bioactive substance covering the exposed surface of the adhesive matrix (col. 4 lines 47-52). Therefore, Haralambopoulos does teach a transdermal patch comprising a liner wherein a dried pharmaceutical composition is present on an exposed surface of the liner (claim 1).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 38 is rejected again under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos (US 5958447). The teachings of Haralambopoulos are outlined above. In column 6, line 47, Haralambopoulos disclose an active substance (or mixture of substances) in powder form can be sprinkled or spread uniformly as a thin layer on an exposed surface adhesive surface of a patch. Additionally, Haralambopoulos teaches ascorbic acid can be combined and formulated with additional carriers, i.e. glycerin, propylene glycol, polypropylene glycol, polyethylene glycol, ethanol, lanolin, and mineral oils (col. 12 line 30).

In view of modern pharmaceutical practice, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a buffering agent or a preservative into a mixture of substances, including a bioactive substance, in powder form into the transdermal patch of Haralambopoulos because Haralambopoulos disclose a bioactive substance and/or a mixture of substances can be successfully incorporated into a transdermal patch (claim 38).

Applicant's arguments have been fully considered but they are not persuasive for the same reasons noted above. Specifically, that Haralambopoulos teaches a transdermal patch

comprising a liner wherein a dried pharmaceutical composition is present on an exposed surface of the liner (Figure 1; claim 1).

Claims 26, 28-29, 32-33 are rejected again under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos (US 5958447) in view of Sintov et al. (US 6274166). The teachings of Haralambopoulos are outlined above. Haralambopoulos does not teach insulin as an active agent.

Sintov et al. teach a transdermal delivery system comprising an active ingredient selected from the group consisting of peptides, proteins, and mixtures thereof. Topical proteins such as insulin can be incorporated into pharmaceutically acceptable carriers such as gels, ointments, solutions, paste, powder, and an adhesive patch (col. 3 lines 53-56). Further, Sintov et al. disclose the therapeutic proteins and its protectors/stabilizers can be applied as a topical formulation such as a cream, ointment, or gel (col. 4 lines 43-45). Sintov et al. disclose a transdermal patch can consist of several layers including the drug layer containing the adhesive polymer, plasticizer, oxidizing agents, penetration enhancers and other excipients (col. 4 lines 50-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a dried pharmaceutical composition comprising insulin with additional agents such as stabilizers and/or polymers into the transdermal patch of Haralambopoulos because Sintov et al. teach topical proteins such as insulin can be incorporated into pharmaceutically acceptable carriers and stabilizers in the form of a powder in a transdermal delivery system and Haralambopoulos teach powdered bioactive substances can be spread

uniformly as a thin layer on an exposed surface adhesive surface of a patch (claims 26, 28-29, 32-33).

Applicant's arguments have been fully considered but they are not persuasive for the same reasons noted above. Specifically, that Haralambopoulos teaches a transdermal patch comprising a liner wherein a dried pharmaceutical composition is present on an exposed surface of the liner (Figure 1; claim 1).

Claims 27, 29, 32-34 are rejected again under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos (US 5958447) in view of Marin (US 6274582). The teachings of Haralambopoulos are outlined above. Haralambopoulos does not teach human growth hormone as an active agent.

Marin teaches human growth hormone (hGH) can be used in combination with a cortisol synthesis inhibitor in a pharmaceutical composition. Marin discloses hGH formulations may be lyophilized in order to obtain a dry powder (col. 5 lines 27-28). Further, compositions which comprise hGH and saccharose are also disclosed (col. 5 lines 30-32). Marin also discloses the hGH compositions can be formulated as transdermal patches (col. 5 lines 40-41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a dried pharmaceutical composition comprising hGH and saccharose into the transdermal patch of Haralambopoulos because Marin teaches hGH formulations may be lyophilized to obtain a dry powder and formulated into a transdermal patch and

Haralambopoulos teach powdered bioactive substances can be spread uniformly as a thin layer on an exposed surface adhesive surface of a patch (claims 27, 29, 32-34).

Applicant's arguments have been fully considered but they are not persuasive for the same reasons noted above. Specifically, that Haralambopoulos teaches a transdermal patch comprising a liner wherein a dried pharmaceutical composition is present on an exposed surface of the liner (Figure 1; claim 1).

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos (US 5958447) in view of Jang (US 5611806). The teachings of Haralambopoulos are outlined above. Haralambopoulos does not teach two electrodes integrated into the patch.

Jang teaches Korean patent publication 92-2264 discloses a patch-type device for transdermally delivering insulin to patients (col. 1 line 48). The insulin delivery patch-type device comprises an insulin solvent reservoir constituting a water-swellable, high molecular, insulin-carrying layer on which insulin is dispersed in a powder form, a needle support adapted to expand as the insulin solvent is discharged from the reservoir and an electrode attached to the ceiling of the reservoir (col. 1 lines 50-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to integrate electrodes into the transdermal patch of Haralambopoulos because Jang teaches an electrode can be integrated into a patch-type device used for the transdermal delivery of a bioactive substance to patients. The motivation to do so is also given by Jang, which

discloses that the electrode supplies the bodily skin with electricity; therefore, penetrating the barrier and allowing a more efficient delivery of the drug and/or medication.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-26, 29-36, 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 18-19 of copending Application No. 11327016. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the '016 claims are both drawn to a printed patch comprising a dried pharmaceutical composition comprising a polypeptide. Additionally, both the instant claims and the '016 claims also recite further elements such as stabilizers, i.e. carbohydrates, amino acids, polymers, and disaccharides that can be added and/or incorporated into the dried pharmaceutical composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

December 20, 2006

M. Monshi

MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER